REMARKS/ARGUMENTS

1. Response to the Rejection under 35 USC §103(a)

Claims 11-16 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Pearlman et al. (WO/9918800) in view of Huet et al. (U.S. 6,426,333). This rejection is respectfully traversed.

Applicant submits that nothing in the art of record teaches or suggests the subject matter positively recited in the amended independent Claim 11.

More specifically, as recited in the independent Claim 11, Applicant's claimed dermatological composition consists of an avermectin compound in a concentration from about 0.05% to about 0.1% (w/v) in a lotion comprising glycerin, hydrogenated polyisobutene, cetearyl alcohol, polyoxyethylene ether of cetyl and stearyl alcohol, macadamia nut oil, dimethicone, tocopheryl acetate, stearoxytrimethylsilane, stearyl alcohol, panthenol, farnesol, benzyl alcohol, phenoxyethanol, acrylates/C10-30 alkyl acrylate crosspolymer, sodium hydroxide, citric acid, and water.

It is important to understand that Applicant's claimed composition is used for treating various forms of dermatological conditions, which requires daily application for a substantial period of time, i.e., from several weeks to several months. Applicant has discovered that the instant dermatological composition containing a very low concentration of ivermectin from 0.05% to 0.1% is effective in treating various dermatological conditions without causing skin irritation, or increase of skin sensitivity after daily use of the instant composition for a substantial period of time up to several months (see Examples 4-14, particularly Example 9).

Therefore, Applicant's topical composition containing a very low concentration of ivermectin in a lotion defined in Claim 11 has strong clinical advantages in treating the dermatological conditions described above.

Applicant submits that Pearlman et al. teach away from Applicant's claimed composition containing a very low concentration of ivermectin for treating dermatological conditions without causing skin irritation.

Pearlman et al. teach methods and kits for removing, treating or preventing head lice infestations in patients, which includes application of a pediculocide, together with the pediculostatic agent, where the pediculocide includes pyrethrins, permethrin, lindane, malation, carbaryl, and ivermectin. Pearlman et al. specifically teach that the pediculocides active ingredients can be used at levels effective to achieve their intended results of treating head lice infestations, which are at a concentration from about 0.25% to about 2.5% (see page 6, third paragraph).

Pearlman et al. further teach to use Cetaphil lotion as a pediculostatic agent and ivermectin as a pediculocide at a concentration of from about 0.25% to about 2.5% to treat head lice for one or a few times, with a limited skin contact time with the topic composition.

Therefore, contrary to Applicant's claimed invention as defined in Claim 11, Pearlman et al's method requires a substantially higher ivermectin concentration in order to be effective to treat head lice infestations. It is noted that the lowest concentration of ivermectin in Pearlman et al.'s composition is 2.5 times higher than the highest concentration of Applicant's claimed composition.

It is clear that Pearlman et al. not only fail to teach or recognize the clinical need and advantages of using a low concentration of ivermectin in combination with a Cetaphil lotion, they teach against such a low concentration to achieve the desired activity for their purpose.

The deficiencies of Pearlman et al. are not overcome by Huet et al.

Huet et al teach spot-on formulations for combating parasites, which comprise a combination of a 1-phenylpyrazole derivative (compound A) and a macrocyclic lactone (compound B) which exhibit synergistic activity against parasites (column 4, lines 17-21). The macrocyclic lactone includes avermectins, ivermectin, abamectin, doramectin, moxidectin, selamectin, milbemycins and their derivatives.

Huet et al specifically teach that a single formulation containing the compounds (A) and (B) in a liquid carrier and in a form which makes possible a single application, or an application repeated a small number of times, will be administered to the animal over a highly localized region of the animal, and it has been discovered that such a

formulation is highly effective against both the targeted ectoparasites and the targeted endoparasites (column 9, lines 15-23).

In Example 7, as referred by the Examiner, Huet et al teach a group of formulations that comprise 10% fipronil (compound A discussed above) and ivermectin at different concentrations including 0.1%, 0.25%, 0.5% and 1%.

Therefore, Huet et al teach using a combination of 1-phenylpyrazole derivative and ivermectin in a spot-on composition, and using the synergistic activities of the two compounds to effectively treat parasites.

Applicant respectfully points out that Huet et al do not teach a topical composition containing 0.1% ivermectin alone, in the absence of the compound A of 1-phenylpyrazole derivative, and do not teach that a composition containing 0.1% ivermectin alone is effective for their intended use.

In this context, Huet et al teach away from Applicant's claimed topical composition consisting of an avermectin compound in a concentration from about 0.05% to about 0.1%. Moreover, based on Huet et al's teaching, one ordinary skilled in the art would not use 0.1% ivermectin alone in a topical composition, because Huet et al explicitly teaches a combination of 1-phenylpyrazole derivative and ivermectin, and the technical advantages of such a combination.

On the other hand, as discussed above, Pearlman et al. teach that ivermectin concentration from 0.25% to 2.5% in the topical composition is the level deemed effective for treating head lice infestations, nothing below that.

Based on such combined teachings, one ordinary skilled in the art would have no reason to choose the lowest concentration of 0.1% ivermectin from Huet et al, which should not be used in the absence of 1-phenylpyrazole derivative, and to combine it with Pearlman et al's Cetaphil, at a concentration of ivermectin that is not deemed effective by Pearlman et al.

Therefore, Applicant maintains that Applicant's claimed dermatological composition defined in the amended Claim 11 is unobvious in view of the prior art of record.

With regard to Claims 12-16, these claims are dependent upon independent Claim 11. Under the principles of 35 U.S.C. §112, 4th paragraph, all of the limitations of each independent claim are recited in its respective dependent claims. As described above, independent Claim 11 is not obvious, as such Claims 12-16 are submitted as being allowable over the art of record.

Accordingly, Applicant respectfully requests withdrawal of the rejection under 35 U.S.C. §103(a).

It is respectfully submitted that Claims 11-16, the pending claims, are now in condition for allowance and such action is respectfully requested.

Applicant's Agent respectfully requests direct telephone communication from the Examiner with a view toward any further action deemed necessary to place the application in final condition for allowance.

5/26/2009
Date of Signature

By: _____
Yi Li
Registration No. 44,211
Agent of the Applicant

Please address correspondence to:

Customer No. **27353**